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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 7

Complete if Known	
Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/KC/	AA	US-6,913,768	07-05-2005	Couch et al.	
/KC/	AB	US-6,764,696	07-20-2004	Pather et al.	
/KC/	AC	US-6,749,867	06-15-2004	Robinson et al.	
/KC/	AD	US-6,605,300	08-12-2003	Burnside et al.	
/KC/	AE	US-6,322,819	11-27-2001	Burnside et al.	
/KC/	AF	US-5,846,568	12-08-1998	Olinger et al.	
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/KC/	AR	US-3,066,075	11-27-1962	DEUTSCH MARSHALL E	
/KC/	AS	US-3,048,526	08-07-1962	C. L. Boswell	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
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/KC/	BC	WO-WO00/25752	05-11-2000	John G Devane		
/KC/	BD	AU-109,438	01-11-1940	I. Lipowski		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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/KC/	CB	Agyilirah GA and Banker SB, Polymers for Enteric Coating applications, Polymers for Controlled Drug Delivery (Peter J. Tarcha ed. 1991) 39-66	
/KC/	CC	American Chemical Society, Polymer Preprints, pp. 633-634, Vol. 34, No. 1, March 1993	
/KC/	CD	Ansel, et al., Rate Controlled Dosage Forms and Drug Delivery Systems, Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed. (1995), 213-222	
/KC/	CE	Answering Expert Report of Dr. Alexander M. Klibanov, expert for Shire Laboratories, Inc., April 25, 2005	
/KC/	CF	Answering Expert Report of Robert Langer, Sc. D. Regarding United States Patent Nos. 6,322,819 and 6,605,300, expert for Shire Laboratories Inc., dated April 25, 2005	
/KC/	CG	Barr Laboratories' Objections and Responses to Plaintiff Shire Laboratories Inc.'s Fifth Set of Interrogatories (No. 17), dated September 3, 2004	
/KC/	CH	Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC	
/KC/	CI	Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, dated September 25, 2003	
/KC/	CJ	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Second Set of Interrogatories (Nos. 8-11), dated February 18, 2004	
/KC/	CK	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Fourth Set of Interrogatories (Nos.15-16), dated July 9, 2004	
/KC/	CL	Barr Laboratories' Memorandum in Support of Its Motion to Amend Its Pleadings and exhibits thereto, dated September 10, 2004	
/KC/	CM	Barr Laboratories' Memorandum in Support of Its Motion to Compel Production, dated September 13, 2004	
/KC/	CN	Barr Laboratories' Supplemental Objections and Responses to Plaintiff Shire Laboratories Inc.'s Third Set of Interrogatories (Nos. 12-14)(Redacted), dated August 27, 2004	
/KC/	CO	Barr Laboratories, Inc.'s '300 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)	
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Examiner's signature	/Kendra Carter/	Date Considered	04/12/2007

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 7

Complete if Known	
Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

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/KC/	CK1	Deposition of Transcript of Charlotte M. McGuiness, dated 8/6/04	
/KC/	CL1	Deposition of Transcript of Donald John Treacy, Jr., dated 8/31/04	
/KC/	CM1	Deposition of Transcript of Edward Rudnic, dated 7/28/04	
/KC/	CN1	Deposition of Transcript of James J. Harrington, dated July 27, 2005	
/KC/	CO1	Deposition of Transcript of Kimberly Fiske, dated 9/17/04	
/KC/	CP1	Deposition of Transcript of Richard Rong-Kun Chang, dated 1/20/05	
/KC/	CQ1	Deposition of Transcript of Richard A. Couch, dated 9/14/04	
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(Use as many sheets as necessary)

Sheet 4 of 7

Complete if Known	
Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

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/KC/	CS2	Impax Laboratories, Inc.'s Memorandum in Support of the Motion to Amend Its Answer dated 2/25/05 and exhibits thereto	
/KC/	CT2	Impax Laboratories, Inc.'s Reply Memorandum in Support of the Motion to Amend Its Answer dated 3/18/05 and exhibits thereto	
/KC/	CU2	Impax Laboratories, Inc's First Amended Answer and Affirmative Defenses, dated May 2, 2005	
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Sheet 5 of 7

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First Named Inventor	Beth A. Burnside
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Attorney Docket Number	20342/1202653-US3

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/KC/	CP3	Response to Office Action filed July 18, 2006 in U.S. Patent Application No. 11/091,010	
/KC/	CQ3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed October 10, 2006	
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/KC/	CS3	Opening Expert Report of Dr. Michael Mayersohn, expert for Impax Laboratories Inc. and exhibits thereto , March 12, 2005	
/KC/	CT3	Opening Expert Report of Dr. Walter Chambliss, expert for Impax Laboratories, Inc. and exhibits thereto, March 15, 2005	
/KC/	CU3	Order Construing The Terms Of U.S. Patent Nos. 6,322,819 And 6,605,300 *Shire Laboratories, Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-CV-01164-GMS	
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/KC/	CH4	Remington's Pharmaceutical Sciences, Fifteenth Edition (1975) 1624-1625	
/KC/	CI4	Remington's Pharmaceutical Sciences, RPS XIV, 1700-1714	
/KC/	CJ4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmatice Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-1219-PKC	
/KC/	CK4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmatice Defenses And Counterclaims *Shire Laboratories, Inc. v. Barr Laboratories, Inc.*, Civil Action No. 03-CV-6632-PKC	
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/KC/	CZ4	Teva Notice letter dated June 1, 2005	
/KC/	CA5	The Merck Index: Amphetamine, 12th Ed., 620	
/KC/	CB5	The Merck Index: Amphetamine, 13th Ed. (2001), 97, 1089	
/KC/	CC5	The United States Pharmacopeia 23, National Formulary 18 (1995) pp. 1791-1799	
/KC/	CD5	The United States Pharmacopeia 26, National Formulary 21 (2003) pp. 2157-2165	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 7

Complete if Known	
Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

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/KC/	CM5	Court Docket for Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated January 8, 2007	
/KC/	CN5	Complaint in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., and exhibits thereto, Case No. 2:06 -cv-00952-SD dated March 2, 2006	
/KC/	CO5	Answer and Counterclaims in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated July 24, 2006	
/KC/	CP5	Reply To Counterclaims in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated August 16, 2006	
/KC/	CQ5	Defendants' Responses to Plaintiff Shire's First Set of Interrogatories (1-12) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated September 20, 2006	
/KC/	CR5	Defendants' Responses to Plaintiff's First Set of Request for the Production of Documents and Things (1-70) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 4, 2006	
/KC/	CS5	Plaintiff's Response to Defendants' First Set of Interrogatories in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 11, 2006	
/KC/	CT5	Plaintiff's Response to Defendants' First Set of Production Requests in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated October 11, 2006	
/KC/	CU5	Defendants' Responses to Plaintiff's Second Set of Requests for the Production of Documents and Things (71-80) in Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd., Case No. 2:06-cv-00952-SD dated November 8, 2006	
/KC/	CV5	Defendants' Responses to Plaintiff Shire's Second Set of Interrogatories (No. 13) in Shire Laboratories v. Teva Pharmaceuticals Industries Ltd., Case No. 2:06-cv-00952-SD dated November 8, 2006	
/KC/	CW5	Petition Under Section 8 and exhibits thereto, submitted to the Canadian Patent Office on December 4, 2006	
/KC/	CX5	Office Action in U.S. Patent Application Serial No. 11/091,011, mailed December 1, 2006	
/KC/	CY5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,011	
/KC/	CZ5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,010	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

Complete If Known	
Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1615
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

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/KC/	BA	EP-0640337	03-01-1995	Ss Pharmaceutical Co		

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/KC/	CA	European Office Action dated January 19, 2007 issued for corresponding European Patent Application No. 99970594.0.	

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Attorney Docket Number	20342/1202653-US3

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/KC/	NPLD1	Amendment After Final Rejection, dated April 21, 2003, filed in U.S. Patent Application No. 09/807,462 (now U.S. Patent No. 6,605,300).	

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Sheet 1 of 4

Complete if Known	
Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	Pharma-0142-C02

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/KC/	A3	6,183,780	B1	Van Balken et al.	02/06/2001	
/KC/	A4	6,214,379	B1	Hermelin	04/10/2001	
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/KC/	B2	WO	00/35450			06/22/2000		
/KC/	B3	WO	00/35426			0622/2000		
/KC/	B4	WO	99/30694			06/24/1999		
/KC/	B5	WO	97/03672			02/06/1997		
/KC/	B6	EP	0 212 747			03/04/1987		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-0142-C02

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/KC/	A26	5,616,345		Geoghegan et al.	04/01/1997	
/KC/	A27	5,395,628		Noda et al.	03/07/1995	
/KC/	A28	5,407,686		Patel et al.	04/18/1995	
/KC/	A29	5,364,620		Geoghegan et al.	11/15/1994	
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/KC/	A41	4,917,899		Geoghegan et al.	04/17/1990	
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/KC/	A48	5,837,284		Mehta et al.	11/1998	

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/KC/	B7	WO	00/23055			04/27/2000		
/KC/	B8	WO	87/00044			01/15/1987		
/KC/	B9	WO	90/09168			08/23/1990		

Examiner Signature	/Kendra Carter/	Date Considered	04/12/2007

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Sheet 3 of 4

Complete if Known	
Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-0142-C02

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
/KC/	C1	K. S. PATRICK et al., " Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit..." HUMAN PSYCHOPHARMACOLOGY, Vol. 12, pp. 527-546, 1997.	
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/KC/	C5	S.B. SPARBER et al., "Amphetamine Cumulation and Tolerance Development: Concurrent and Opposing Phenomena," PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR, Vol. 20, pp, 415-424, 1984.	
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/KC/	C11	Barr Laboratories' Answer, Affirmative Defenses and Counterclaim in Case No. 03-CV-1219(VM)(DFE) (S.D.N.Y.)	

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/KC/	C12	WALIA et al., Preliminary Evaluation of an Aqueous Wax, Emulsion for Controlled-Release Coating, Pharm. Dev. Tech., vol. 3, no. 1, pp. 103-113 (1998).	
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Examiner Signature	/Kendra Carter/	Date Considered	04/12/2007

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